FEB 2 3 2001

K 010021

510(k) SUMMARY

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-0818 Fax
Contact:	Florence A. Caikoski Regulatory Affairs Associate
Date Prepared:	December 11, 2000

B. Trade Name: Medcomp Quad Lumen Central Venous Catheter

Common Name: Catheter, Intravascular, Therapeutic, Short-term, Less than 30 days

Classification: FOZ

C.F.R. Section: 880.5200

C. Predicate Device: K962577 ~~K862056~~ Arrow-Howes Quad Lumen Central Venous Catheter

D. Device Description:

The Medcomp Quad Lumen Central Venous Catheter is a 8.5F x 20cm polyurethane catheter intended to provide central venous access. The four circular lumen passages are 16GA, 18GA, 14GA, and 18GA. The lumens are connected to the extensions via a soft pliable hub with suture wing. Each extension is labeled with gauge size and lumen designation for ease in identification. The lumen is printed with depth markings to facilitate correct placement of the catheter tip. The largest lumen extends to the distal tip, the remaining lumens exit at side holes near the distal tip. The soft, flexible distal tip reduces the potential for vessel perforation.

E. Intended Use:

The Medcomp Quad Lumen Central Venous Catheter is indicated for use in attaining short-term vascular access for the administration of nutritional replacement therapy and the infusion of medications and solutions. It may be inserted percutaneously and is primarily placed in the internal jugular vein. Alternate insertion site is the subclavian vein as required.

F. Comparison to Predicate Device:

The technological characteristics of the Medcomp Quad Lumen Central Venous Catheter are substantially equivalent to the predicate device in terms of intended use, insertion method, anatomical location, design, materials, performance, manufacturing process and method of sterilization.

The difference between these devices is the inner lumen shape and the size of the side holes. In addition, the predicate device indications for use does not specify the types of solutions that may be infused.

G. Performance Data:

In Vitro performance data for the Medcomp Quad Lumen Catheter, including tensile strength, joint strength, air leakage, liquid leakage, and flow performance demonstrate that this device is substantially equivalent to legally marketed devices intended for central venous catheterization.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 23 2001

Ms. Florence A. Caikoski
Regulatory Affairs Associate
Medical Components, Incorporated
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K010021
Trade Name: Medcomp Quad Lumen Central Venous Catheter
Regulatory Class: II
Product Code: FOZ
Dated: December 11, 2000
Received: January 3, 2001

Dear Ms. Caikoski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K010021

Device Name: Medcomp Quad Lumen Central Venous Catheter

Indications for use:

The Medcomp Quad Lumen Central Venous Catheter is designed for the administration of nutritional replacement therapy and the infusion of medications and solutions.

It may be inserted percutaneously and is primarily placed in the internal jugular vein.

Alternate insertion sites include the subclavian vein as required.

This catheter is intended for short term vascular access.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K010021